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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,483	09/28/2005	Joerg Rosenberg	M/42135	5340

26474 7590 04/13/2009

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,483	ROSENBERG ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 01/09/09 are acknowledged.

2. The Request for Continued Examination filed on 12/09/08 is acknowledged.

3. New claims 21-22 were added.

4. Claims 1-22 are included in the prosecution.

Continued Examination under 37 CFR 1.114

5. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/09/08 has been entered.

Response to Arguments

Rejection of claims 1-4, 6-8 and 10-19 under 35 USC § 103(a)

6. Applicant's arguments, see Page 6, filed 01/09/09, with respect to the rejection of claims 1-4, 6-8 and 10-19 under 35 USC § 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Carli (US 4,632,828) have been fully considered and are found persuasive. Therefore, the rejection of 07/09/08 is maintained.

However, upon further consideration, a new ground(s) of rejection is made in over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1)

Rejection of claim 5 under 35 USC § 103(a)

7. Applicant's arguments, see Page 6, filed 01/09/09, with respect to the rejection of claim 5 under 35 USC § 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Carli (US 4,632,828) and Endicott et al. (US 3,087,860) have been fully considered and are found persuasive. Therefore, the rejection of 07/09/08 is maintained.

However, upon further consideration, a new ground(s) of rejection is made over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1) and further in view of Endicott et al. (US 3,087,860).

Rejection of claims 9 and 20 under 35 USC § 103(a)

8. Applicant's arguments, see Page 6, filed 01/09/09, with respect to the rejection of claims 1-4, 6-8 and 10-19 under 35 USC § 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Carli (US 4,632,828) and Goertz et al. (US 4,801,460) have been fully considered and are found persuasive. Therefore, the rejection of 07/09/08 is maintained.

However, upon further consideration, a new ground(s) of rejection is made over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1) and further in view of Goertz et al. (US 4,801,460).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-4, 6-8, 10-19 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1).

The claimed invention is a process for producing solid dosage forms comprising forming a moldable cohesive composition which comprises:

a) 50 to 99.4% by weight of at least one crosslinked nonthermoplastic carrier,

b) 0.5 to 30% by weight of at least one adjuvant (selected from the group consisting of thermoplastic polymers, lipids, sugar alcohols, sugar alcohol derivatives and solubilizers) and

c) 0.1 to 49.5% by weight of at least one active ingredient.

The moldable cohesive composition is formed by heating at a temperature at or above the softening point of the adjuvant, but at least 70°C, in a multi-screw extruder and subsequently cooled.

Klimesch teaches "a continuous process for the preparation of solid pharmaceutical forms by extruding a polymer melt containing the active compound and forming the still plastic extrudate between a belt and a roller or two belts" (Col. 1, lines 5-9). Klimesch teaches that "it is as a rule substantially more advantageous if the extruder is in the form of a conventional single-screw or multi-screw mixing extruder, so that premixing is unnecessary" (Col. 1, lines 31-34). "Shaping takes place directly after the extrusion process. The still plastic extrudate is passed, if necessary with the aid of a suitable guide channel ... through the shaping apparatuses ..." (Col. 1, lines 48-51).

Klimesch teaches that "extrudable pharmaceutical mixtures are mixtures of one or more pharmaceutical active compounds with one or more auxiliaries which are conventionally used in the preparation of pharmaceutical tablets and are pasty and therefore extrudable due to the melting or softening of one or more components" (Col. 3, lines 1-6). Pharmacologically acceptable polymers such as polyvinylpyrrolidone (PVP) and copolymers of N-vinylpyrrolidone (NVP) and vinyl acetate are disclosed (Col. 3, lines 6-12). Example 3 discloses crosslinked PVP as a tablet disintegrant (Col. 6, lines 52-53). Pharmacologically acceptable plasticizers such as fatty acid esters are disclosed (Col. 3, lines 29-38). Conventional pharmaceutical auxiliaries such as silicates, stearic acid or its salts with magnesium, lactose, cereal starch, corn starch or potato starch are also disclosed (Col. 4, lines 30-36). Active compounds are disclosed as substances having a pharmaceutical action and a very low level of side effects, provided that they do not decompose under the processing conditions, and the concentration of the active compound may be from 0.1% to 95% (Col. 4, lines 57-68 and Col. 5, line 1 to Col. 6, line 3). Theophylline is the active compound used in examples 1-14 (Col. 6, line 23 to Col. 8, line 21). Example 3 discloses: "47.5 parts of a copolymer having a K value of 30 and consisting of 60% by weight of N-vinylpyrrolidone and 40% by weight of vinyl acetate, 2.5 parts of crosslinked PVP as a tablet disintegrant and 50 parts of theophylline were mixed and extruded in a twin-screw extruder. The temperatures of the five shots were each 120ºC, and the die was at 130ºC. The still plastic extrudate was pressed to give oblong tablets as in Example 1 (temperature of the double link belt: +15 ºC). The tablets were stable to mechanical effects" (Col. 6, lines 49-59).

Klimesch does not expressly teach a high level (50-99.4%) of crosslinked nonthermoplastic carrier.

Thacharodi teaches a process for making a pharmaceutical composition which comprises "mixing together a substituted pyridylsulfinyl benzimidazole ... with a pharmaceutically acceptable carrier, the carrier comprising at least one polymer which is at least partially comprised of vinylpyrrolidone monomeric units, together with any optionally included pharmaceutically acceptable excipients" (Page 3, [0012]). The pharmaceutically acceptable carrier is present in an amount from about 10% to about 98% by weight of the total weight of the composition (Page 5, [0020]). Fatty acid glycerides may also be used as pharmaceutically acceptable carriers (Page 5, [0022]). The fatty acid glyceride is "heated to above its melting point and the liquid obtained [is] mixed with other ingredients of the composition to obtain granules" (Page 5, [0023]). Example 6 discloses the heating of fatty acid glycerides (AKOMED R at 13.33% and GELUCIRE at 6.67%) to 60ºC. After cooling the fatty acid glycerides to 30ºC, a blend of the active ingredient (omeprazole at 13.33%) and cross-linked polyvinylpyrrolidone (KOLLIDON CL-M at 66.67%) was granulated with the fatty acid glycerides (Page 7, [0037] and Table 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a process for the preparation of solid pharmaceutical forms by extruding a polymer melt containing the active compound and forming the still plastic extrudate between a belt and a roller or two belts, as taught by Klimesch, combine it with the process of making a granular pharmaceutical composition with a high

percentage (10 to 98%) of a pharmaceutically acceptable carrier such as cross-linked polyvinylpyrrolidone (Kollidon CL-M), as taught by Thacharodi, and produce the instant invention.

One of ordinary skill in the art would do this because the use of a high level of cross-linked polyvinylpyrrolidone (KOLLIDON CL-M at 66.67%) in a stable oral pharmaceutical composition is known in the art, as evidenced by Thacharodi (Page 7, [0037], Table 7 and Page 8, Tables 9 and 10). Combining prior art elements according to known methods to yield predictable results would have been obvious to one of ordinary skill in the art. Please see MPEP 2141.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of the process of heating the components in a multi-screw extruder would have been obvious over the process of extruding a polymer melt containing the active compound and the multi-screw mixing extruder, as taught by Klimesch (Col. 1, lines 5-9 and Col. 1, lines 31-34). The limitation of forming a moldable cohesive composition would have been obvious over the plastic extrudate that was pressed to give oblong tablets (Col. 6, Example 3, lines 49-59). The limitation of the crosslinked nonthermoplastic carrier would have been obvious over the crosslinked PVP taught by Klimesch (Col. 6, Example 3, lines 52-53) and over the

cross-linked polyvinylpyrrolidone (KOLLIDON CL-M at 66.67%), as taught by Thacharodi (Page 7, [0037] and Table 7). The percentage (50 to 99.4%) of the crosslinked nonthermoplastic carrier would have been obvious over the cross-linked polyvinylpyrrolidone (KOLLIDON CL-M) used at 66.67% in Example 6 by Thacharodi (Page 7, [0037] and Table 7). One with ordinary skill in the art would use a high percentage of the polymer which functions as a disintegrant in order to optimize the desired release rate of the chose active ingredient. One of ordinary skill in the art would increase the disintegrant level in order to increase the rate of disintegration of the composition. The limitation of the adjuvant would have been obvious over the 13.33% (calculated 20mg/150mg = 13.33% by weight) of AKOMED R (lipid component) in Example 6, as disclosed by Thacharodi (Page 7, [0037] and Table 7). The limitation of the active ingredient would have been obvious over the active compounds that may be from 0.1% to 95%, as taught by Klimesch (Col. 4, lines 57-68 and Col. 5, line 1 to Col. 6, line 3). The limitation of heating at a temperature at or above the softening point of the adjuvant, but at least at 70ºC, would have been obvious over the polymeric binder that "must soften or melt at from 50 to 180º C., ... so that the mass is extrudable", as taught by Klimesch (Col. 3, lines 24-26). The limitation of the multi-screw extruder would have been obvious over the advantageous multi-screw mixing extruder taught by Klimesch (Col. 1, lines 30-35). The limitation of subsequently cooling the moldable composition would have been obvious over the pressing of the extrudate to give oblong tablets "using a double link belt which was cooled to 15º C", as taught by Klimesch (Col. 6, lines 30-32).

Regarding instant claim 2, the limitation of the weight percentage of the crosslinked nonthermoplastic carrier would have been obvious over the cross-linked polyvinylpyrrolidone (KOLLIDON CL-M) used at 66.67% in Example 6 by Thacharodi (Page 7, [0037] and Table 7). The limitation of 5 to 30% of a thermoplastic carrier would have been obvious over the pharmaceutically acceptable carrier (present in an amount from about 10% to about 98%) comprising at least one polymer which is at least partially comprised of vinylpyrrolidone monomeric units, as taught by Thacharodi (Page 3, [0012]). The limitation of 0.5 to 20% of a solubilizer would be obvious over the solubilizers AKOMED R (caprylic/capric triglyceride at 13.33%) and GELUCIRE (glycerol esters of C_8-C_{18} fatty acids at 6.67%) as taught by Thacharodi (Page 7, [0037] and Table 7). The limitation of 0.1 to 45.5% of at least one active ingredient would have been obvious over the active compounds that may be from 0.1% to 95%, as taught by Klimesch (Col. 4, lines 57-68 and Col. 5, line 1 to Col. 6, line 3) and over the 13.33% of active (omeprazole at 13.33%) taught by Thacharodi (Page 7, [0037] and Table 7).

Regarding instant claim 3, the crosslinked nonthermoplastic carrier would have been obvious over the crosslinked PVP taught by Klimesch (Col. 6, Example 3, lines 52-53) and the cross-linked PVP taught by Thacharodi (Page 7, [0037] and Table 7).

Regarding instant claim 4, the thermoplastic polymer would have been obvious over the copolymers of N-vinylpyrrolidone (NVP) and vinyl acetate, as taught by Klimesch (Col. 3, lines 6-12).

Regarding instant claim 6, the lipid would have been obvious over the fatty acid esters (Col. 3, lines 29-38) and stearic acid (Col. 4, lines 30-36) as taught by Klimesch

and over the AKOMED R (lipid component) in Example 6, as disclosed by Thacharodi (Page 7, [0037] and Table 7).

Regarding instant claim 7, the solubilizer would have been obvious over the fatty acid esters taught by Klimesch (Col. 3, lines 29-38) and over the solubilizers AKOMED R (caprylic/capric triglyceride at 13.33%) and GELUCIRE (glycerol esters of C_8-C_{18} fatty acids at 6.67%) taught by Thacharodi (Page 7, [0037] and Table 7).

Regarding instant claim 8, the limitation of the solubility of the active ingredient would have been obvious over the active compounds taught by Klimesch which include poorly water-soluble drugs such as betamethasone and acetylsalicylic acid (Col. 4, lines 57-68 and Col. 5, line 1 to Col. 6, line 3).

Regarding instant claim 10, the limitation of the tableting aid would have been obvious over the conventional pharmaceutical auxiliaries such as silicates, stearic acid or its salts with magnesium, lactose, cereal starch, corn starch or potato starch disclosed by Klimesch (Col. 4, lines 30-36).

Regarding instant claims 11-13, the limitations of components a) – c) that are mixed before heating, during heating and after heating would have been obvious over the process of mixing and extruding the components of the composition taught by Klimesch (Col. 6, lines 49-59). One with ordinary skill in the art would do this because during the process of routine experimentation the order of mixing and heating can be manipulated in order to achieve the desired attributes of the finished dosage form.

Regarding instant claim 14, the limitation of the moldable cohesive composition that is homogenized to distribute the active ingredient would have been obvious over

the process of mixing and extruding the components of the composition taught by Klimesch (Col. 6, lines 49-59). One with ordinary skill in the art would ensure that the active ingredient was uniformly distributed in the composition by the process of mixing and extruding.

Regarding instant claim 15, the limitation of melting the adjuvant with the nonthermoplastic carrier and admixing the active ingredient would have been obvious over the process of extruding taught by Klimesch (Col. 6, lines 49-59) because during the process of routine optimization one with ordinary skill in the art would modify the order to adding the active ingredient to the other components in order to ensure uniformity.

Regarding instant claims 16-17, the residence time would have been obvious over the extrusion process taught by Klimesch (Col. 6, lines 49-59) because the residence time is a manipulatable parameter and one with ordinary skill in the art would increase or decrease the residence time of the composition in the multi-screw extruder during the process of routine experimentation. The recited residence time frames would have been obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claim 18, the limitations of shaping the molded cohesive composition between at least one belt and at least one roll would have been obvious over the extrusion of a polymer melt containing an active compound and forming the still plastic extrudate between a belt and a roller or two belts, as taught by Klimesch (Col. 1, lines 5-9).

Regarding instant claim 19, the limitations of shaping the molded cohesive composition by calendaring would have been obvious over the calendaring taught by Klimesch (Col. 1, lines 10-12).

Regarding instant claim 21, the limitation of the temperature range from 70ºC - 180 ºC, would have been obvious over the polymeric binder that "must soften or melt at from 50 to 180º C., ... so that the mass is extrudable", as taught by Klimesch (Col. 3, lines 24-26).

Regarding instant claim 22, the limitation of the process that is carried out in the absence of a solvent would have been obvious over the process where the active is sparingly soluble in water and forms a molecular disperse phase in the polymer melt without the addition of solvents, as taught by Klimesch (Col. 12, claim 14).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1) and further in view of Endicott et al. (US 3,087,860).

The teachings of Klimesch and Thacharodi are stated above.

Klimesch and Thacharodi do not expressly teach sugar alcohols as adjuvants.

Endicott teaches adjuvants such as sorbitol and mannitol (Col. 3, lines 67-70) and teaches that a drug-plastic combination can be mixed and extruded (Col. 4, lines 21-23).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a process for the preparation of solid pharmaceutical forms by extruding a polymer melt containing the active compound and forming the still plastic

extrudate between a belt and a roller or two belts, as taught by Klimesch, combine it with the process of making a granular pharmaceutical composition with a high percentage (10 to 98%) of a pharmaceutically acceptable carrier such as cross-linked polyvinylpyrrolidone (Kollidon CL-M), as taught by Thacharodi, further combine it with the use of adjuvants such as sorbitol and mannitol in an extrudable drug/plastic composition, as taught by Endicott, and produce the instant invention.

One of ordinary skill in the art would have done this because sugar alcohols such as sorbitol and mannitol are known in the art to be used as excipients or adjuvants and can be included in extrudable compositions, as evidenced by the teaching of Endicott.

Regarding instant claim 5, the limitation of the sugar alcohol would have been obvious over the sorbitol and mannitol taught by Endicott (Col. 3, lines 67-70).

12. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1) and further in view of Goertz et al. (US 4,801,460).

The teachings of Klimesch and Thacharodi are stated above.

Klimesch and Thacharodi do not expressly teach the cooled composition that is comminuted and compressed to the dosage form.

Goertz teaches a process for the preparation of solid pharmaceutical forms by mixing one or more pharmaceutical active compounds with one or more fusible, pharmacologically tolerated binders and subjecting the mixture to extrusion and shaping, wherein the fusible binder used is a solvent-free NVP polymer (Col. 1, line 64 to Col. 2, line 4). "Shaping may be effected by injection molding or by extrusion followed

by shaping of the plastic extrudate, for example by hotface cutting to give granules or molding to give tablets ... cold-face cutting is also suitable and may be followed by pressing of the granules to give tablets" (Col. 5, lines 11-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a process for the preparation of solid pharmaceutical forms by extruding a polymer melt containing the active compound and forming the still plastic extrudate between a belt and a roller or two belts, as taught by Klimesch, combine it with the process of making a granular pharmaceutical composition with a high percentage (10 to 98%) of a pharmaceutically acceptable carrier such as cross-linked polyvinylpyrrolidone (Kollidon CL-M), as taught by Thacharodi, further combine it with the cold-face cutting to give granules, as taught by Goertz, and produce the instant invention.

One of ordinary skill in the art would have done this because Goertz teaches the formation of tablets from the granules.

Regarding instant claim 9, the limitation of the cooled composition that is comminuted and compressed to the dosage form would have been obvious over the granules formed from the extruded composition, as taught by Goertz (Col. Col. 5, lines 11-20).

Regarding instant claim 20, the limitation of hot or cold cutting to form small-particle granules would have been obvious over the hot or cold cutting to form granules of the extruded composition, as taught by Goertz (Col. Col. 5, lines 11-20).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615